

GMP AUDIT CERTIFICATE

Rephine hereby certifies that a Good Manufacturing Practices (GMP) audit was completed at the company's facilities located at

Audit Date

2025/03/13 - 2025/03/13

ALPAVIT

**Kemptener Straße 17 – 24, 87493
Lauben/Allgäu**

Regulatory frame

EU Directive 2001/83/EC (and amendments 2004/27/EC and 2011/62/EU), 21 CFR 210 & 211 and UK Human Medicines Regulations 2012 (SI 2012/1916).

Reference to

The correspondent guidance **IPEC - PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients**.

The products in the audit scope encompassed **Excipients**.

The audit was carried out following the rules and methodology set forth in Rephine's Quality System based on **ISO 9001 & ISO 17020**

The results of this audit are described in a full report, filled by Rephine. The report is available to the interested parties, and bound by the terms and conditions of confidentiality, agreed with the audited

Certificate Number

AUD-3513

Validity for
3 years

José Carlos Vergara
Technical Director

Date

Signature accepted

Signed By: José Carlos Vergara

Signed Date: 24/04/2025 15:05

Signed Id: [a5eNw000002kztyIAA](#)

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